

FORM PTO-1390 (Modified)  
(REV. 11-2000)

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTORNEY'S DOCKET NUMBER

**TRANSMITTAL LETTER TO THE UNITED STATES  
DESIGNATED/ELECTED OFFICE (DO/EO/US)  
CONCERNING A FILING UNDER 35 U.S.C. 371**

200.1156US

U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR

**10/524334**INTERNATIONAL APPLICATION NO.  
**PCT/US03/25601**INTERNATIONAL FILING DATE  
**August 15, 2003**PRIORITY DATE CLAIMED  
**August 15, 2002**

TITLE OF INVENTION

**PHARMACEUTICAL COMPOSITIONS**

APPLICANT(S) FOR DO/EO/US

**Benjamin OSHLACK, Hua-Pin HUANG, Rampurna Prasad GULLAPALLI, Meredith MACHONIS.**

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☒ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (24) indicated below.
4. ☒ The US has been elected by the expiration of 19 months from the priority date (Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371 (c) (2))
  - a. ☒ is attached hereto (required only if not communicated by the International Bureau).
  - b. ☐ has been communicated by the International Bureau.
  - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
  - a. ☐ is attached hereto.
  - b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))
  - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
  - b. ☐ have been communicated by the International Bureau.
  - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
  - d. ☒ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).
10. ☐ An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).
11. ☒ A copy of the International Preliminary Examination Report (PCT/IPEA/409).
12. ☒ A copy of the International Search Report (PCT/ISA/210).

**Items 13 to 20 below concern document(s) or information included:**

13. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
14. ☒ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
15. ☒ A **FIRST** preliminary amendment.
16. ☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
17. ☐ A substitute specification.
18. ☐ A change of power of attorney and/or address letter.
19. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821 - 1.825.
20. ☐ A second copy of the published international application under 35 U.S.C. 154(d)(4).
21. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
22. ☒ Certificate of Mailing by Express Mail Label No. **EV 382 793 948 US**
23. ☒ Other items or information:

- Letter re Priority;  
- Application Data Sheet.

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**10/524334**INTERNATIONAL APPLICATION NO.  
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24. The following fees are submitted:

CALCULATIONS PTO USE ONLY

☒ a) Basic national fee..... \$300.00

☒ b) Examination fee..... \$200.00

☒ c) Search fee..... \$500.00

**TOTAL OF ABOVE CALCULATIONS = \$1000.00**

**ENTER APPROPRIATE BASIC FEE AMOUNT =****\$1,000.00**Surcharge of \$130.00 for furnishing the oath or declaration later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492 (e)).**\$0.00**

| CLAIMS   | NUMBER FILED | NUMBER EXTRA | RATE                     |
|--|--------------|--------------|--------------------------|
| Total claims                                     | 36 - 20 =    | 16           | x \$50.00                |
| Independent claims                               | 5 - 3 =      | 2            | x \$200.00               |
| Multiple Dependent Claims (check if applicable). |              |              | <input type="checkbox"/> |

**\$0.00****TOTAL OF ABOVE CALCULATIONS =****\$2,200.00**☐ Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.**\$0.00****SUBTOTAL =****\$2,200.00**Processing fee of \$130.00 for furnishing the English translation later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492 (f)).**\$0.00****TOTAL NATIONAL FEE =****\$2,200.00**

Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31) (check if applicable).

☒**\$40.00****TOTAL FEES ENCLOSED =****\$2,240.00**

|               |    |
|---------------|----|
| Amount to be: | \$ |
| refunded      |    |
| charged       | \$ |

- a. ☒ A check in the amount of **\$2,240.00** to cover the above fees is enclosed.
- b. ☐ Please charge my Deposit Account No. \_\_\_\_\_ in the amount of \_\_\_\_\_ to cover the above fees.
- c. ☒ The Director is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. **50-0552**
- d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

Davidson, Davidson & Kappel, LLC  
485 Seventh Avenue, 14th Floor  
New York, NY 10018  
(212) 736-1940

SIGNATURE

Robert J. Paradiso

NAME

41,240

REGISTRATION NUMBER

February 11, 2005

DATE

DT01 Rec'd PCT/PTC

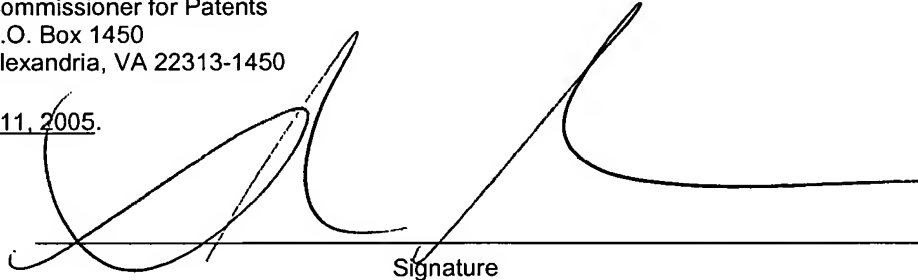
10/524334  
11 FEB 2005

### Certificate of Express Mailing under 37 CFR 1.10

I hereby certify that this correspondence is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. § 1.10 in an envelope addressed to:

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Re.: Docket No.: 200.1156US  
Applicant(s): Benjamin OSHLACK, et al.  
Serial No.: To be Assigned  
Invention: PHARMACEUTICAL COMPOSITIONS  
Filing Date: Herewith as National Phase of International Patent Application No. PCT/US03/25601 filed on August 15, 2003.

Enclosed are:

- Transmittal Letter Concerning a Filing under 35 USC 371(2 pages) ;
- International Patent Application PCT/US03/025601(37 pages);
- Letter re Priority (1 page);
- Preliminary Amendment (8 pages);
- Application Data Sheet (2 pages);
- Executed Declaration and Power of Attorney (6 pages);
- Recordation Form Cover Sheet along with Assignment (7 pages)
- A copy of the International Preliminary Examination Report (6 pages)
- A copy of the International Search Report (5 Pages);
- Check in the amount of \$ 2,240.00

This collection of information is required by 37 CFR 1.10. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1.8 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.